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EXAMINER

CHISM, BILLY D

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 03/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/693,908

Applicant(s)

HERMONAT, PAUL L.

Examiner

Billy D Chism

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-- The MAILING DATE of this communication app ars on th cover she t with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_ .
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

**DETAILED ACTION****INSERT A**

Applicant's election of Group II, claims 1-20 with traverse in Paper No. 7 (USPTO mailroom date of 1 Nov 2001 is acknowledged. The traversal is on the ground(s) that Groups I and II are necessarily examined together because a search for the polypeptide would have resulted in a search of the DNA. This is not found persuasive a DNA is not the same molecule as a protein nor is a protein the same molecule as a DNA. In Addition, the search for the polypeptide(s) is not coextensive. A search for the polypeptide would not have resulted in a complete search of the DNA. Attention is directed to the prior Office Action indicating that Groups I and II are separately classified and searched. There is no factual data of record that substantiates applicant's comment of coextensive search. The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as indefinite since it is not clear whether "modified protein" is an AAV Rep 78 mutant or an AAV Rep78 modified protein (i.e., with an insertion, deletion, or substitution) as stated in the claim or whether modified refers to, e.g. N and/or C-terminal substituents and/or side chain modifications. Claim 1 is also indefinite regarding the statement

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“possesses different biochemical and biological functions as compared to wild-type AAV.”

Additionally, claim 1 should read “adeno-associated virus” instead of the abbreviation AAV.

The abbreviation is adequate for all subsequent claims. See also deletion of “comprising an AAV Rep78 modified.” As to what is the “wild-type protein”, the claim is unclear as to which sequence is considered as the wild-type

Claim 2 is rejected for indefinite wording of “bind differently.” Claim 2 rejected as indefinite since it is not clear whether the claimed invention is an AAV Rep 78 mutant or an AAV Rep 78 modified protein as stated in the claim. See also the claim 1 dependency.

Claims 2-20 are rejected for depending from indefinite claim 1.

Claim 6 is rejected as indefinite regarding limitation because not clear as to meaning of “combination thereof.” What are the “combinations” and what specific residues are included in each combination. Additionally, claim 6 rejected for being dependent on indefinite claim 2.

Claim 7 is rejected as indefinite regarding limitation because not clear as to location or size of “minimum number of amino acids.” Additionally, claim 7 rejected for being dependent on indefinite claim 6.

Claims 8-10 rejected for being dependent on indefinite claim 7.

Claim 9 is rejected as indefinite for lack of identifying relevant SEQ ID Number. Claim 9 also rejected for being dependent on indefinite claim 8.

Claim 13 and 19 rejected for enlarging the scope of claim 1 by including an AAV Rep78 protein that is not recited in claim 1, i.e., no antecedent basis for fusion protein per se in claim 1.

Claims 13 and 19 rejected for being dependent on indefinite claim 1.

Claims 14-20 are rejected for being dependent on indefinite claim 13.

*Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-4, 6, 8, 9, and 11 rejected under 35 U.S.C. 102(a) as being taught by Zhan, et al. 1999. J. of Biol. Chem., vol. 274, no. 44, pp. 31619-31624. Zhan et al. teach AAV Rep78 mutants (Rep-77<sup>LG</sup>) with different functions (see page 31621, paragraph bridging left and right columns) that disclose mutations with defective binding as compared to the wild-type AAV Rep78 protein. Zhan et al. (page 31622) also teach binding to the p97 HPV-16 promoter region of human papillomavirus DNA by AAV Rep78 mutant. Additionally, Zhan et al. teach the substitution mutant AAV Rep-77<sup>LG</sup>, (see page 31620, left column).

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5. Claims 1 and 2 rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava et al., 1983 (J. of Vir., vol. 45, no. 2, p. 555-564) or Chiorini et al., 1998 (WO 98/11244). Srivastava et al., 1983 (page 561-62), anticipate a modified AAV Rep78 protein. Chiorini et al. (pages 17-18 and 22) anticipate modified AAV Rep78 proteins.

6. Claims 13 and 16 rejected under 35 U.S.C. 102(b) as being taught by Batchu et al., 1995, Biochemical and Biophysical research Communications, vol. 210, no. 3, pp 717-725. Batchu et al., 1995 (page 719), teach a MBP-AAV Rep78 mutant fusion protein.

7. Claims 1 and 2 rejected under 35 U.S.C. 102(e) as being anticipated by Russel et al., U.S. Patent No. 6,156,303, (pp. 19-20 and Fig 3). Russell et al. patent discloses and claims an AAV Rep78 modified protein

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

BDC

25 Mar 2002

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